QUALITY CONTROL FUNCTIONS
of The Analytical Laboratory at
The Medical Supply Depot, Auckland Park, Johannesburg

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The analytical laboratory was founded in the late 1960’s with the express function of ensuring strict quality control on all medicines destined for the Provincial Hospital Services of the then Transvaal. The laboratory’s function remains to ensure that all products that are on Government tender and destined for use in the Provincial Hospitals and clinics in Gauteng, comply with the suppliers’ and manufacturers’ specifications.

With the large increase in generic product availability, there is a real and urgent need for the development of a dedicated laboratory that will monitor both State and Private pharmaceutical products. This comment is prompted by the fact that while some companies produce dedicated batches for State issue only, most generic pharmaceutical companies supply both the private and public sectors with the same batches of medicine.

Processes
1. The analytical processes used are UV-vis spectrophotometry, near-infrared spectrophotometry, thin layer chromatography, polarimetry, pH measurement, conductivity measurement, mass spectrophotometry and several other procedures, such as titrations and BP identifications.
2. The quantitative measurements are verified by means of UV spectrophotometry, IR spectrophotometry, polarimetry, mass spectrophotometry and BP assays, whilst qualitative measurements are verified by thin layer chromatography, pH measurement and conductivity.
3. All product labelling is checked as per Act 101 (1965).

Protocol followed for products that do not meet the required specifications
1. The supplier is notified of the problem and invited to comment.
2. Tests are repeated at the laboratory, and the supplier is requested to furnish a Certificate of Analysis for that particular batch.
3. Should there still be a conflict between the laboratory and the supplier, samples of the batch are sent to the SABS which acts as arbitrator.
4. In the event of the product being sub-standard, the Medicines Control Council is informed and the product is withdrawn from circulation.

Examples of substandard products
Table 1 shows some products which were determined to have been sub-standard over the past two years. These reflect some of the most serious aberrations. Figures 1 to 3 are examples of UV scans obtained for some of the products.

It appears that in Gauteng there are two different approaches towards medicine quality control. In the public sector, there is proactive quality control – all medicines destined for the State hospitals and clinics are checked prior to issue. In the private sector, it appears that the situation is mostly reactive. In other words, it is likely that a product will...
It appears that the solution absorbed an unknown component which is not detected by HPLC.

The solution absorbed ink from the label. Corrected, but will reject in future.

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